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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,596	02/12/2002	Michael G. Rosenblum	CLFR:007US/GNS	4852

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,596

Applicant(s)

ROSENBLUM ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36, 50-61 and 89-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-57 and 59-61 is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13, 15-17, 20-25, 28, 58 and 89-98 is/are rejected.
- 7) ☒ Claim(s) 6-11, 14, 18, 19, 26, 27 and 29-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/2002; 5/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1653

Applicant's election without traverse of Invention 1, Claims 1-36, 50-61, and 89-98 in the reply filed on July 5, 2005 is acknowledged.

Claims 37-49 and 62-88 have been canceled. Claims 1-36, 50-61, and 89-98 are currently pending and are under examination.

Priority is to February 12, 2001.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 88, line 3 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 95, 96, and 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 58, it appears that the entire gelonin polypeptide is the antigenic region, or fragment of the entire gelonin polypeptide.

In Claims 95, the term "upstream" is generally used to refer to DNA that is 5' to another sequence. When making fusion proteins, polypeptides are N- or C-terminal to another polypeptide.

Claim 96 depends from Claim 89, and therefore there is no antecedent basis for the antibody.

Art Unit: 1653

Claim 98 is awkward because the antibody of Claim 96 would be considered to be the heterologous polypeptide.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Better et al. (1994; J. Biological Chemistry 269(13): 9644-9650).

Better et al. teach gelonin analogues having mutations at Lys10Cys, Asn60Cys, Asn239Cys, Lys244Cys, Asp247Cys, Lys248Cys, Cys50Ala, Cys44Ala, Cys44Ala+Cys50Ala, Lys10Cys+Cys44Ala+Cys50Ala, and Asp247Cys+Cys44Ala+Cys50Ala.

Therefore, Better et al. teach a gelonin toxin that is not SEQ ID NO: 1 but retains the amino acids 110-210 of SEQ ID NO: 1 (Claim 1), plus 10 (Claim 2), plus 20 (Claim 3), plus 30 (Claim 4) and plus 50 (Claim 5) contiguous amino acids from SEQ ID NO: 1 (See Table 1).

The gelonin analogues were conjugated to murine H65 antibody which recognizes CD5 antigen in human T cells (Claims 12, 13, 15-17).

Claims 20-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (1997; FEMS Microbiology Letters 146:91-96).

Johnson et al. replaced the immunogenic loop within diphtheria toxin with an epitope from the major outer membrane protein of *N. meningitidis*.

Art Unit: 1653

Claims 20-25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Suhrbier et al. (1991; J. Immunology 147(8): 2507-2513).

Suhrbier et al. substituted amino acid within the epitope YSYFDSVI (amino acids 593-600) of tetanus toxin.

Claims 89-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Parakh et al. (1995; Proceedings of the American Association for Cancer Research Annual Meeting 36:488, abstract # 2909).

Parakh et al. teach a polypeptide comprising gelonin and a single chain monoclonal antibody (Claims 89-92).

The antibody was derived from murine monoclonal antibody ZME-018 (Claim 93) and the antibody was a single chain analogue of ZME-018, sFvSME-018. Claim 94 is included in this rejection because there does not appear to be a difference between the claimed sFvMEL and Parakh et al.'s sFvZME-018 because both the antibodies are directed against melanoma cells A375 (see spec page 13, para. 2, and page 15 at Fig 6, for example).

The sFvZME-018 appears to have been placed N-terminal or "upstream" of gelonin because Parakh et al. state that the DNA encoding sFvZME-018 was linked to gelonin, rather than stating that the gelonin was linked to sFvZME-018 (Claim 95). The linker was a short peptide (Claims 96-98).

Art Unit: 1653

Claims 1-5, 12, 13, 15-17, 20-25, 28, 58, and 89-98 are rejected.

Claims 6-11, 14, 18, 19, 26, 27, and 29-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 50-56, 57, and 59-61 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Karen Cochrane Carlson" followed by a circular stamp containing the letters "PC".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER